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IS 13450 (Part 2/Sec 7) : 2006
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[Superseding IS 7620 (Part 1) : 1986]

भारतीय मानक

चिकित्सीय विद्युत उपस्कर

भाग 2 सुरक्षा के लिए विशिष्ट अपेक्षाएँ

अनुभाग 7 उच्च-वोल्टता जनित्रों वाले नैदानिक क्ष-किरण जनित्रों

Indian Standard

MEDICAL ELECTRICAL EQUIPMENT

PART 2 PARTICULAR REQUIREMENTS FOR THE SAFETY

Section 7 High-Voltage Generators of Diagnostic X-Ray Generators

ICS 11.040.50

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BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

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Price Group 12

AMENDMENT NO. 1 DECEMBER 2008
TO
IS 13450 (PART 2/SEC 7) : 2006/IEC 60601-2-7 (1998)
MEDICAL ELECTRICAL EQUIPMENT

(*National Foreword*, *last paragraph*) — Insert the following new paragraphs at the end:

'The standard also makes a reference to the BIS Certification Marking of the product, details of which is given in National Annex A.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be same as that of the specified value in this standard.'

(*Page* 39) — Insert the following National Annex A at the end of the standard:

'NATIONAL ANNEX A

(National Foreword)

A-1 BIS CERTIFICATION MARKING

The product may also be marked with the Standard Mark.

A-1.1 The use of the Standard Mark is governed by the provisions of the *Bureau of Indian Standards Act*, 1986 and the rules and regulations made thereunder. The details of the conditions under which the license for the use of Standard Mark may be granted to manufacturers or producers may be obtained from Bureau of Indian Standards.'

(MHR 18)

Reprography Unit, BIS, New Delhi, India

Electromedical Equipment Sectional Committee, MHR 15

NATIONAL FOREWORD

This Indian Standard (Part 2/Sec 7) which is identical with IEC 60601-2-7 (1998) 'Medical electrical equipment — Part 2-7 : Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators' issued by the International Electrotechnical Commission (IEC) was adopted by the Bureau of Indian Standards on the recommendation of the Electromedical Equipment Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

This standard was first published in 1975 and will supersede existing Indian Standard IS 7620 (Part 1) : 1986 'Medical electrical equipment — Diagnostic X-ray equipment: Part 1 Mechanical and electrical safety requirements' to incorporate latest modern technologies.

The text of the IEC Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.

b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

The technical committee responsible for the preparation of this standard has reviewed the provisions of the following International Standards and has decided that they are acceptable for use in conjunction with this standard:

International Standard	*Title*
IEC 60601-1 (1988)[1]	Medical electrical equipment — Part 1 : General requirements for safety
IEC 60601-1-3 (1994)	Medical electrical equipment — Part 1-3 : General requirements for safety — Collateral standard : General requirements for radiation protection in diagnostic X-ray equipment
IEC/TR 60788 (2004)	Medical electrical equipment — Glossary

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[1] Since revised in 2005.

Indian Standard

MEDICAL ELECTRICAL EQUIPMENT

PART 2 PARTICULAR REQUIREMENTS FOR THE SAFETY

Section 7 High-Voltage Generators of Diagnostic X-Ray Generators

SECTION 1: GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies except as follows:

1.1 Scope

Replacement:

This Particular Standard applies to HIGH-VOLTAGE GENERATORS of medical diagnostic X-RAY GENERATORS and to their subassemblies including the following:

- HIGH-VOLTAGE GENERATORS that are integrated with an X-RAY TUBE ASSEMBLY;
- HIGH-VOLTAGE GENERATORS of radiotherapy treatment simulators.

Where appropriate, requirements for X-RAY GENERATORS are given but only where these concern the functioning of the associated HIGH-VOLTAGE GENERATOR.

This standard excludes

- CAPACITOR DISCHARGE HIGH-VOLTAGE GENERATORS (these are covered by IEC 60601-2-15),
- HIGH-VOLTAGE GENERATORS for mammography,
- HIGH-VOLTAGE GENERATORS for RECONSTRUCTIVE TOMOGRAPHY.

1.2 Object

Replacement:

The object of this standard is to establish particular requirements to ensure safety and to specify methods for demonstrating compliance with those requirements.

NOTE 1 – Requirements for reproducibility, linearity, constancy and accuracy are given because of their relationship to the quality and quantity of the IONIZING RADIATION produced, and are confined to those considered necessary for safety.

NOTE 2 – Both the levels for compliance and the tests prescribed to determine compliance reflect the fact that the safety of HIGH-VOLTAGE GENERATORS is not sensitive to small differences in levels of performance. The combinations of LOADING FACTORS specified for the tests are, therefore, limited in number but chosen from experience as being appropriate in most cases. It is considered important to standardize the choice of combinations of LOADING FACTORS so that comparison can be made between tests performed in different places on different occasions. However, combinations other than those specified could be of equal technical validity.

NOTE 3 – The safety philosophy on which this standard is based is described in the introduction to the General Standard and in IEC 60513.

NOTE 4 – Concerning RADIOLOGICAL PROTECTION it has been assumed in the preparation of this standard that MANUFACTURERS and USERS do accept the general principles of the ICRP as stated in ICRP 60, 1990, paragraph 112,[1] namely:

a) "No practice involving exposures to radiation should be adopted unless it produces sufficient benefit to the exposed individuals or to society to offset the radiation detriment it causes. (The justification of a practice.)

b) In relation to any particular source within a practice, the magnitude of individual doses, the number of people exposed, and the likelihood of incurring exposures where these are not certain to be received should all be kept as low as reasonably achievable, economic and social factors being taken into account. This procedure should be constrained by restrictions on the doses to individuals (dose constraints), or the risks to individuals in the case of potential exposures (risk constraints), so as to limit the inequity likely to result from the inherent economic and social judgements. (The optimisation of protection.)

c) The exposure of individuals resulting from the combination of all the relevant practices should be subject to dose limits, or to some control of risk in the case of potential exposures. These are aimed at ensuring that no individual is exposed to radiation risks that are judged to be unacceptable from these practices in any normal circumstances. Not all sources are susceptible of control by action at the source and it is necessary to specify the sources to be included as relevant before selecting a dose limit. (Individual dose and risk limits)."

NOTE 5 – Most of the requirements on X-RAY EQUIPMENT and its subassemblies for protection against IONIZING RADIATION are given in the Collateral Standard IEC 60601-1-3.

This standard does, however, deal with some aspects of RADIOLOGICAL PROTECTION, mainly those that depend upon the supply, control and indication of electrical energy from the HIGH-VOLTAGE GENERATOR.

NOTE 6 – It is recognized that many of the judgements necessary to follow the ICRP general principles have to be made by the USER and not by the MANUFACTURER of the EQUIPMENT.

1.3 Particular Standards

Addition:

This Particular Standard, hereinafter referred to as "this standard", amends and supplements a set of IEC publications, hereinafter referred to as "General Standard", consisting of IEC 60601-1: 1988, *Medical electrical equipment – Part 1: General requirements for safety*, its amendments 1 (1991) and 2 (1995), and all Collateral Standards. The numbering of sections, clauses and subclauses of this standard corresponds to that of the General Standard. The changes to the text of the General Standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the General Standard is replaced completely by the text of this standard.

"Addition" means that the text of this standard is additional to the requirements of the General Standard.

"Amendment" means that the clause or subclause of the General Standard is amended as indicated by the text of this standard.

Subclauses or figures which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Where there is no corresponding section, clause or subclause in this standard, the section, clause or subclause of the General Standard applies without modification.

Where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this standard.

A requirement of this standard replacing or modifying requirements of the General Standard takes precedence over the original requirements concerned.

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[1] ICRP Publication 60: Recommendations of the International Commission on Radiological Protection (*Annals of the ICRP* Vol. 21 No 1-3, 1990). Published by Pergamon Press.

1.3.101 Related International Standards

This standard requires HIGH-VOLTAGE GENERATORS, or subassemblies thereof, to comply with the applicable requirements of IEC 60601-1-3.

NOTE – IEC 60601-1-3 contains the following:

"In the following IEC standards, requirements that relate to medical diagnostic X-RAY EQUIPMENT are superseded by the requirements in this Collateral Standard:

IEC 60407: 1973, *Radiation protection in medical X-ray equipment 10 kV to 400 kV*

IEC 60407A: 1975, *First supplement to IEC 60407 .*"

Attention is drawn to the existence of the following IEC publications:

IEC 60417P:1997, *Graphical symbols for use on equipment: Index, survey and compilation of the single sheets – Fifteenth supplement*

IEC 60601-2-15:1988, *Medical electrical equipment – Part 2: Particular requirements for the safety of capacitor discharge X-ray generators*

IEC 60601-2-28:1993, *Medical electrical equipment – Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis*

IEC 60601-2-32:1994, *Medical electrical equipment – Part 2: Particular requirements for the safety of associated equipment of X-ray equipment*

IEC 60613:1989, *Electrical, thermal and loading characteristics of rotating anode X-ray tubes for medical diagnosis*

IEC 60664-1:1992, *Insulation coordination for equipment within low-voltage systems – Part 1: Principles, requirements and tests*

IEC 60788: 1984, *Medical radiology – Terminology*

ISO 497:1973, *Guide to the choice of series of preferred numbers and of series containing more rounded values of preferred numbers*

ISO 3665:1976, *Photography – Intra-oral dental radiographic film – Specifications*

ISO 7000:1989, *Graphical symbols for use on equipment – Index and synopsis*

2 Terminology and definitions

This clause of the General Standard applies except as follows:

Addition before 2.1:

In this standard, terms printed in SMALL CAPITALS are used in accordance with their definitions in the General Standard or in IEC 60788.

NOTE – Attention is drawn to the fact that, in cases where the concept addressed is not strongly confined to the definition given in one of the publications listed above, a corresponding term is printed in lower case letters.

An index of defined terms used in this standard is given in annex AA.

Associated conditions qualifying the usage of certain terms are given in 2.101.

aa) In this standard unless otherwise indicated:

- values of X-RAY TUBE VOLTAGE refer to peak values, transients being disregarded;
- values of X-RAY TUBE CURRENT refer to average values.

bb) The electric power in the high-voltage circuit mentioned in 6.8.2 a) 3) and 6.8.2 a) 4) is calculated according to the formula:

$$P = f\,U\,I$$

where

P is the electric power;

f is the factor depending on the waveform of the X-RAY TUBE VOLTAGE, selected as below and is

a) 0,74 for ONE-PEAK HIGH-VOLTAGE GENERATORS and TWO-PEAK HIGH-VOLTAGE GENERATORS, or

b) 0,95 for SIX-PEAK HIGH-VOLTAGE GENERATORS, or

c) 1,00 for TWELVE-PEAK HIGH-VOLTAGE GENERATORS and CONSTANT POTENTIAL HIGH-VOLTAGE GENERATORS; or

d) for other HIGH-VOLTAGE GENERATORS, the most appropriate value, 0,74, 0,95 or 1,00, chosen according to the waveform of the X-RAY TUBE VOLTAGE, with a statement of the value selected;

U is the X-RAY TUBE VOLTAGE;

I is the X-RAY TUBE CURRENT.

Addition:

2.101 Qualifying conditions for defined terms

2.101.1 Operating conditions for NOMINAL X-RAY TUBE VOLTAGE

NOMINAL X-RAY TUBE VOLTAGE is defined in IEC 60788 (rm-36-03) as the highest permitted X-RAY TUBE VOLTAGE for specific operating conditions. In this standard, if specific operating conditions are not stated, it is to be assumed that the value referenced is unconditional and is thus the highest X-RAY TUBE VOLTAGE permitted for NORMAL USE of the item under consideration. Such a value cannot be higher, but is sometimes lower, than values permitted for certain separate subassemblies or parts of the item.

2.101.2 PERCENTAGE RIPPLE in CONSTANT POTENTIAL HIGH-VOLTAGE GENERATORS

Unless otherwise stated, it is to be assumed that for a HIGH-VOLTAGE GENERATOR to be regarded as a CONSTANT POTENTIAL HIGH-VOLTAGE GENERATOR, the PERCENTAGE RIPPLE of its output voltage (under the relevant conditions) does not exceed 4.

2.101.3 RADIATION QUANTITY for NOMINAL SHORTEST IRRADIATION TIME

The definition of NOMINAL SHORTEST IRRADIATION TIME refers to a required constancy of a RADIATION QUANTITY. In this standard the RADIATION QUANTITY concerned is AIR KERMA.

2.101.4 IRRADIATION TIME

Generally the IRRADIATION TIME is measured in terms of LOADING TIME as the time interval between:

– the instant that the X-RAY TUBE VOLTAGE has risen for the first time to a value of 75 % of the peak value; and

– the instant at which it finally drops below the same value.

For systems in which LOADING is controlled by electronic switching of the high voltage, using a grid in an electronic tube or in the X-RAY TUBE, the LOADING TIME may be determined as the time interval between the instant when the TIMING DEVICE generates the signal to start the IRRADIATION and the instant when it generates the signal to terminate the IRRADIATION.

For systems in which LOADING is controlled by simultaneous switching in the primaries of both the high-voltage circuit and the heating supply for the filament of the X-RAY TUBE, the LOADING time shall be determined as the time interval between the instant when the X-RAY TUBE CURRENT first rises above 25 % of its maximum value and the instant when it finally falls below the same value.

3 General requirements

This clause of the General Standard applies except as follows:

3.1 *Addition:*

HIGH-VOLTAGE GENERATORS shall be designed so as not to deliver in NORMAL USE, to any connected X-RAY TUBE ASSEMBLY, a voltage greater than the NOMINAL X-RAY TUBE VOLTAGE for the X-RAY TUBE ASSEMBLY concerned.

5 Classification

This clause of the General Standard applies except as follows:

5.1 *Replacement:*

HIGH-VOLTAGE GENERATORS shall be CLASS I EQUIPMENT or INTERNALLY POWERED EQUIPMENT.

5.6 *Replacement:*

Unless otherwise specified, HIGH-VOLTAGE GENERATORS or subassemblies thereof shall be classified as suitable for continuous connection to the SUPPLY MAINS in the STAND-BY STATE and for specified LOADINGS; see also 6.1 m) and 6.8.101.

6 Identification, marking and documents

This clause of the General Standard applies except as follows:

6.1 Marking on the outside of EQUIPMENT or EQUIPMENT parts

g) Connection to the supply

Addition:

– For HIGH-VOLTAGE GENERATORS that are specified to be permanently installed, the information required in 6.1 g) of the General Standard may be stated in the ACCOMPANYING DOCUMENTS only.

h) Supply frequency

Addition:

– For HIGH-VOLTAGE GENERATORS that are specified to be permanently installed, the information required in 6.1 h) of the General Standard may be stated in the ACCOMPANYING DOCUMENTS only.

j) Power input

Addition:

For HIGH-VOLTAGE GENERATORS that are specified to be permanently installed, the information may be stated in the ACCOMPANYING DOCUMENTS only.

The information on the input power shall be specified in terms of combinations of

1) the RATED MAINS VOLTAGE of the X-RAY GENERATOR in volts; see item g),
2) the number of phases; see item g),
3) the frequency, in hertz; see item h),
4) the maximum permissible value for APPARENT RESISTANCE OF SUPPLY MAINS, in ohms;
5) the characteristics of OVER-CURRENT RELEASES required in the SUPPLY MAINS.

m) Mode of operation

Replacement:

The mode of operation – where appropriate, together with maximum permissible ratings – shall be stated in the ACCOMPANYING DOCUMENTS; see 6.8.101.

n) Fuses

Addition:

For HIGH-VOLTAGE GENERATORS that are specified to be permanently installed, this subclause of the General Standard does not apply; see item j).

p) Output

Replacement:

This subclause of the General Standard does not apply.

t) Cooling conditions

Addition:

The cooling requirements for the safe operation of a HIGH-VOLTAGE GENERATOR, or a subassembly thereof, shall be indicated in the ACCOMPANYING DOCUMENTS, including as appropriate:

- the maximum heat dissipation into the surrounding air, given separately for each subassembly that dissipates more than 100 W and might be separately located on installation;
- the maximum heat dissipation into forced air cooling devices, and the corresponding flow rate and temperature rise of the forced air stream;
- the maximum heat dissipation into a cooling medium utility and the permissible input temperature range, minimum flow rate and pressure requirements for the utility.

Addition:

aa) Marking of compliance

If, for a HIGH-VOLTAGE GENERATOR or subassembly thereof, compliance with this standard is to be marked on the outside of the EQUIPMENT, such marking shall be made in combination with the MODEL OR TYPE REFERENCE as follows:

[MODEL OR TYPE REFERENCE] IEC 60601-2-7

6.7 Indicator lights and push-buttons

a) Colours of indicator lights

Addition after the first paragraph:

For HIGH-VOLTAGE GENERATORS, the colours to be used for indicator lights shall be as follows:

- the colour green shall be used at the CONTROL PANEL to indicate the state from which one further action leads to the LOADING STATE; see 29.1.102 a);
- the colour yellow shall be used at the CONTROL PANEL to indicate the LOADING STATE; see 29.1.102 b).

NOTE – The colours of indicator lights need to be chosen according to the message to be given. Thus, the same operational state of an EQUIPMENT can have simultaneous indications in different colours depending upon the place of indication, for example green at the CONTROL PANEL and red at the entrance to the EXAMINATION ROOM.

6.8 ACCOMPANYING DOCUMENTS

6.8.2 INSTRUCTIONS FOR USE

a) General information

Addition:

Electric output data shall be stated in the INSTRUCTIONS FOR USE in terms of LOADING FACTORS as described in 6.8.2 a) 1) to 6.8.2 a) 6).

For diagnostic devices in which part of the HIGH-VOLTAGE GENERATOR is integrated with the X-RAY TUBE ASSEMBLY (for example X-RAY TUBE HEADS) the stated values shall refer to the complete device.

The following combinations and data shall be stated:

1) For both CONTINUOUS MODE and INTERMITTENT MODE, the corresponding NOMINAL X-RAY TUBE VOLTAGE together with the highest X-RAY TUBE CURRENT obtainable from the HIGH-VOLTAGE GENERATOR when operated at that X-RAY TUBE VOLTAGE.

2) For both CONTINUOUS MODE and INTERMITTENT MODE, the corresponding highest X-RAY TUBE CURRENT together with the highest X-RAY TUBE VOLTAGE obtainable from the HIGH-VOLTAGE GENERATOR when operating at that X-RAY TUBE CURRENT.

3) For both CONTINUOUS MODE and INTERMITTENT MODE, the corresponding combination of X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT which results in the highest electric output power.

4) The NOMINAL ELECTRIC POWER given as the highest constant electric output power in kilowatts which the HIGH-VOLTAGE GENERATOR can deliver, for a LOADING TIME of 0,1 s at an X-RAY TUBE VOLTAGE of 100 kV or, if these values are not selectable, with an X-RAY TUBE VOLTAGE nearest to 100 kV and the value of LOADING TIME nearest to but not less than 0,1 s.

The NOMINAL ELECTRIC POWER shall be given together with the combination of X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT and the LOADING TIME.

5) For HIGH-VOLTAGE GENERATORS indicating precalculated or measured CURRENT TIME PRODUCT, the lowest CURRENT TIME PRODUCT or the combinations of LOADING FACTORS resulting in the lowest CURRENT TIME PRODUCT.

If the value of the lowest CURRENT TIME PRODUCT depends upon the X-RAY TUBE VOLTAGE or upon certain combinations of values of LOADING FACTORS, the lowest CURRENT TIME PRODUCT may be given as a table or curve showing the dependence.

6) For HIGH-VOLTAGE GENERATORS provided with AUTOMATIC EXPOSURE CONTROL SYSTEMS controlling the IRRADIATION TIME, the NOMINAL SHORTEST IRRADIATION TIME.

If the NOMINAL SHORTEST IRRADIATION TIME depends upon LOADING FACTORS such as X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT, the ranges of these LOADING FACTORS for which the NOMINAL SHORTEST IRRADIATION TIME is valid shall be stated.

For HIGH-VOLTAGE GENERATORS provided with AUTOMATIC EXPOSURE CONTROL SYSTEMS controlling the X-RAY TUBE VOLTAGE or the X-RAY TUBE CURRENT the maximum possible excursion of the X-RAY TUBE VOLTAGE or the X-RAY TUBE CURRENT during the IRRADIATION shall be stated in the INSTRUCTIONS FOR USE.

6.8.3 Technical description

a) General

Addition:

The technical description shall contain information about the combination or, if necessary, the combinations of subassemblies and ACCESSORIES of an X-RAY GENERATOR with which compliance with the requirements of 50.101 and 50.102 can be shown; see 50.1.

NOTE – Attention is drawn to the usefulness in the technical description of

- data and essential characteristics to determine the ratings of an earth leakage circuit breaker, or
- indication of the types of earth leakage circuit breakers which can be used with the HIGH-VOLTAGE GENERATOR.

Addition:

6.8.101 Reference to ACCOMPANYING DOCUMENTS

Clauses and subclauses of this standard in which additional requirements concerning the content of ACCOMPANYING DOCUMENTS are given:

Mode of operation and specified LOADINGS	5.6 and 6.1 m)
Connection to the supply	6.1 g)
Number of phases of SUPPLY MAINS	6.1 g) and 6.1 j) 2)
Frequency of SUPPLY MAINS	6.1 h) and 6.1 j) 3)
Power input	6.1 j)
MAINS VOLTAGE	6.1 j) 1)
APPARENT RESISTANCE OF SUPPLY MAINS	6.1 j) 4) and 10.2.2
OVER-CURRENT RELEASE	6.1 j) 5)
Fuses	6.1 n)
Cooling conditions	6.1 t)
Electric output data, combinations of LOADING FACTORS	6.8.2 a) and 50.101
Suitable combinations for compliance test	6.8.3 a) and 50.1
Earth leakage circuit breaker	6.8.3 a)
Compliance with this standard	6.8.102
Central connection point PROTECTIVE EARTH CONDUCTOR	19.3
Range and interrelation of LOADING FACTORS	29.1.102 e)
Test conditions for automatic control in INTERMITTENT MODE	29.1.102 e)
Method to check the AUTOMATIC INTENSITY CONTROL and AUTOMATIC EXPOSURE CONTROL	29.1.104 f)
Equal intervals on scales	29.1.106 e)
Combinations with the HIGH-VOLTAGE GENERATOR	50.1
Suitable test combinations	50.1
LOADING FACTORS and modes of operation	50.101.1 a)
LOADING FACTORS in fixed combinations	50.101.2 a)
Provisions for semi-permanent values of LOADING FACTORS	50.101.2 b)
Density correction of AUTOMATIC EXPOSURE CONTROL	50.102.2 dd) 2)

6.8.102 Statement of compliance

If, for an X-RAY GENERATOR or a HIGH-VOLTAGE GENERATOR, or a subassembly of the latter, compliance with this standard is to be stated, the statement shall be made in the following form:

X-ray generator [MODEL OR TYPE REFERENCE] IEC 60601-2-7:1998 or

High-voltage generator [MODEL OR TYPE REFERENCE] IEC 60601-2-7:1998 or

[Name of subassembly] [MODEL OR TYPE REFERENCE] IEC 60601-2-7:1998.

SECTION 2: ENVIRONMENTAL CONDITIONS

The clauses and subclauses of this section of the General Standard apply except as follows:

10 Environmental conditions

This clause of the General Standard applies except as follows:

10.2.2 Power supply

Item a)

Addition:

The internal impedance of a SUPPLY MAINS is to be considered sufficiently low for the operation of a HIGH-VOLTAGE GENERATOR if the value of the APPARENT RESISTANCE OF SUPPLY MAINS does not exceed

- the appropriate reference value according to table 101, or
- the value specified according to 6.1 j) 4), whichever is the greater.

Table 101 – Reference values for the APPARENT RESISTANCE OF SUPPLY MAINS

Waveform of high voltage	**NOMINAL ELECTRIC POWER according to 6.8.2 a) 4)** kW	**NOMINAL MAINS VOLTAGE** V							
		480	440	415	400	240	230	208	120
		APPARENT RESISTANCE OF SUPPLY MAINS Ω							
One-peak	0,5					0,95	0,81	0,70	
	1,0	2,4	2,0	1,79	1,66	0,60	0,55	0,45	0,15
	2,0	1,6	1,3	1,19	1,10	0,40	0,36	0,30	0,10
	4,0	1,0	0,80	0,72	0,66	0,24	0,22	0,18	0,06
	8,0	0,50	0,40	0,36	0,33	0,12	0,11	0,09	0,032
	10,0	0,40	0,34	0,30	0,27				
	16,0	0,24	0,20	0,18	0,17				
Two-peak	4,0	1,6	1,3	1,19	1,1	0,40	0,36	0,30	0,10
	8,0	1,0	0,80	0,72	0,66	0,24	0,22	0,18	0,06
	10,0	0,80	0,67	0,60	0,55	0,18	0,18	0,14	0,045
	16,0	0,50	0,40	0,36	0,33	0,12	0,11	0,09	0,032
	20,0	0,40	0,34	0,30	0,27				
	32,0	0,24	0,20	0,18	0,17				
	50,0	0,16	0,14	0,12	0,11				
Six-peak, twelve-peak and up to constant potential	16,0	0,83	0,65	0,60	0,55	0,19	0,18	0,14	0,045
	20,0	0,64	0,50	0,48	0,44	0,14	0,15	0,11	0,035
	32,0	0,40	0,34	0,30	0,27				
	40,0	0,32	0,27	0,24	0,22				
	50,0	0,24	0,20	0,18	0,17				
	75,0	0,16	0,14	0,12	0,11				
	100	0,12	0,10	0,09	0,09				
	150	0,08	0,07	0,06	0,056				

A supply derived from a local electric power generator is considered suitable only if it is approved as such by the MANUFACTURER of the HIGH-VOLTAGE GENERATOR.

NOTE – If a NOMINAL voltage is claimed for a mains power supply system, it is assumed that there is no voltage of a higher value between any of the conductors of the system, or between any of these conductors and earth.

An alternating voltage is considered in practice to be sinusoidal if any instantaneous value of the waveform concerned differs from the instantaneous value of the ideal waveform at the same moment by no more than ±2 % of the peak value of the ideal waveform.

A three-phase SUPPLY MAINS is considered to have a practical symmetry if it delivers symmetrical voltages and produces, when loaded symmetrically, symmetrical currents.

Symmetrical voltages are considered to exist, if, when determined according to Fortescue's theorem [2]*, neither the magnitude of the negative sequence voltages nor the magnitude of the zero sequence voltages exceeds 2 % of the magnitude of the positive sequence voltages.*

Symmetrical currents are considered to exist if, when determined according to Fortescue's theorem [2]*, neither the magnitude of the negative sequence currents, nor the magnitude of the zero sequence currents exceeds 5 % of the magnitude of the positive sequence currents.*

NOTE – The requirements of this standard are based upon the assumption that three-phase systems have a symmetrical configuration of the MAINS VOLTAGE with respect to earth and include a neutral conductor, and that single-phase systems are derived from such three-phase systems. Where the supply system is not earthed at the source it is assumed that adequate measures have been provided to detect, limit and remedy any disturbance of symmetry within a reasonably short time.

A HIGH-VOLTAGE GENERATOR is considered to comply with the requirements of this standard only if its specified NOMINAL ELECTRIC POWER can be demonstrated at an APPARENT RESISTANCE OF SUPPLY MAINS having a value not less than the relevant reference value in table 101 or not less than the APPARENT RESISTANCE OF SUPPLY MAINS specified according to 6.1 j) 4), whichever is the greater.

For this purpose, the APPARENT RESISTANCE OF SUPPLY MAINS R is determined according to the formula:

$$R = \frac{U_0 - U_1}{I_1}$$

where

U_0 is the no-load MAINS VOLTAGE;

U_1 is the MAINS VOLTAGE under load;

I_1 is the mains current under load.

The MAINS VOLTAGE shall be measured between

- phase and neutral in a single-phase system,
- phase and phase in a two-phase system,
- each two phases in a three-phase system.

The APPARENT RESISTANCE OF SUPPLY MAINS shall be measured by applying a single resistive load of a value corresponding approximately to the NOMINAL ELECTRIC POWER specified according to 6.8.2 a) 4), but not more than 30 kW.

Reference values for the APPARENT RESISTANCE OF SUPPLY MAINS for NOMINAL MAINS VOLTAGES not included in table 101 may be interpolated or extrapolated, and shall be calculated on the basis that the reference value is proportional to the square of the NOMINAL MAINS VOLTAGE.

If values of NOMINAL ELECTRIC POWER between those given in table 101 are specified, it shall be possible to fulfil all requirements applying for the next lower value of NOMINAL ELECTRIC POWER given in table 101 with the APPARENT RESISTANCE OF SUPPLY MAINS given for that lower value.

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[2] C. L. Fortescue, Method of symmetrical co-ordinates applied to the solution of polyphase networks, *Trans. AIEE.* vol. 37, pp. 1027 - 1140, 1918.

SECTION 3: PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

The clauses and subclauses of this section of the General Standard apply except as follows:

15 Limitation of voltage and/or energy

This clause of the General Standard applies except as follows:

Addition:

aa) Detachable HIGH-VOLTAGE CABLE CONNECTIONS shall either be designed so that the use of TOOLS is required to disconnect them or they shall be provided with INTERLOCKS so that at all times when PROTECTIVE COVERS or high-voltage connections are removed

- the HIGH-VOLTAGE GENERATOR is disconnected from its power supply, and
- capacitances in the high-voltage circuit are discharged within the minimum time necessary to gain access to the high-voltage circuit, and
- the discharged state is maintained.

Compliance is checked by inspection and by measurement.

bb) Provision shall be made to prevent the appearance of an unacceptably high voltage in the MAINS PART or in any other low-voltage circuit.

NOTE – This may be achieved for example

- by provision of a winding layer or a conductive screen connected to the PROTECTIVE EARTH TERMINAL between high-voltage and low-voltage circuits,
- by provision of a voltage limiting device across terminals to which external devices are connected and between which an excessive voltage might arise if the external path becomes discontinuous.

Compliance is checked by inspection of design data and construction.

16 ENCLOSURES and PROTECTIVE COVERS

This clause of the General Standard applies except as follows:

Addition:

NOTE – Requirements concerning the resistance and earthing of a flexible conductive screen of high-voltage cables connected to X-RAY TUBE ASSEMBLIES are given in IEC 60601-2-28.

19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

This clause of the General Standard applies except as follows:

19.3 Allowable values

Addition:

For HIGH-VOLTAGE GENERATORS and subassemblies thereof the column on Type B and the rows on EARTH LEAKAGE CURRENT, in NORMAL CONDITION and SINGLE FAULT CONDITION and on ENCLOSURE LEAKAGE CURRENT, in NORMAL CONDITION, of table IV including the notes of the General Standard apply.

The allowable values of EARTH LEAKAGE CURRENT are permitted for each subassembly of an X-RAY EQUIPMENT that is supplied by its own exclusive connection to the SUPPLY MAINS or to a central connection point, if the latter is fixed and permanently installed.

A fixed and permanently installed central connection point may be provided inside the outer ENCLOSURE or cover of the HIGH-VOLTAGE GENERATOR. If other subassemblies such as an X-RAY SOURCE ASSEMBLY or ASSOCIATED EQUIPMENT are connected to the central connection point, the EARTH LEAKAGE CURRENT between such a central connection point and the external protective system may exceed the allowable values for any one of the single devices connected.

NOTE – The limitation of the EARTH LEAKAGE CURRENTS within the environment of an X-RAY EQUIPMENT is intended to ensure that ACCESSIBLE PARTS do not become live and to prevent interference in other electrical equipment.

The provision of a central connection point is acceptable, as for fixed and permanently installed EQUIPMENT, the interruption of the PROTECTIVE EARTH CONDUCTOR is not considered to be a SINGLE FAULT CONDITION. However, in such cases, adequate information on the combination of subassemblies needs to be provided in accordance with 6.8.3 a).

19.3 a), table IV, note 3)

Addition:

For permanently installed HIGH-VOLTAGE GENERATORS, the EARTH LEAKAGE CURRENT under NORMAL CONDITION and SINGLE FAULT CONDITION shall not exceed 10 mA.

19.3 a), table IV, note 4)

Addition:

For MOBILE X-RAY EQUIPMENT and TRANSPORTABLE X-RAY EQUIPMENT, the EARTH LEAKAGE CURRENT under NORMAL CONDITION shall not exceed 2,5 mA and under SINGLE FAULT CONDITION shall not exceed 5 mA. The ENCLOSURE LEAKAGE CURRENT under SINGLE FAULT CONDITION shall not exceed 2 mA.

19.3 b), table IV, note 3)

Addition:

For permanently installed HIGH-VOLTAGE GENERATORS, regardless of waveform and frequency, the EARTH LEAKAGE CURRENT under NORMAL CONDITION and SINGLE FAULT CONDITION shall not exceed 20 mA.

20 Dielectric strength

This clause of the General Standard applies except as follows:

20.3 Values of test voltages

Addition:

The dielectric strength of the electrical insulation of high-voltage circuits shall be sufficient to withstand the test voltages for the durations given in 20.4 a) and in table 102.

The test shall be made without an X-RAY TUBE connected and with a test voltage of 1,2 times the NOMINAL X-RAY TUBE VOLTAGE of the HIGH-VOLTAGE GENERATOR.

If the HIGH-VOLTAGE GENERATOR can be tested only with the X-RAY TUBE connected and if the X-RAY TUBE does not allow the HIGH-VOLTAGE GENERATOR to be tested with a test voltage of 1,2 times the NOMINAL X-RAY TUBE VOLTAGE, the test voltage shall be lower but not less than 1,1 times that voltage.

Addition

20.3.101 For ONE-PEAK HIGH-VOLTAGE GENERATORS, the test voltage for the high-voltage circuit shall be referred to the no-load half cycle if the X-RAY TUBE VOLTAGE for the no-load half cycle is higher than in the on-load half cycle.

20.3.102 For HIGH-VOLTAGE GENERATORS intended for operation in both INTERMITTENT MODE and CONTINUOUS MODE, and in which the NOMINAL X-RAY TUBE VOLTAGE for CONTINUOUS MODE does not exceed 80 % of that for INTERMITTENT MODE, the test voltage for the high-voltage circuit shall be referred to the value for INTERMITTENT MODE, and the test shall be carried out in that mode only.

20.4 Tests

Item *a)*

Addition:

The high-voltage circuits of HIGH-VOLTAGE GENERATORS or subassemblies thereof are tested by applying a test voltage of 50 % of its final value according to 20.3 and raising it over a period of 10 s to the final value which is then maintained for the duration given in table 102.

If during the dielectric strength test there is a risk of overheating a transformer under test, it is permitted to carry out the test at a higher supply frequency.

Table 102 – Duration of dielectric strength test

High-voltage circuits tested in:	Duration *)
INTERMITTENT MODE	3 min
CONTINUOUS MODE	15 min

*) For testing with an X-RAY TUBE see 20.4 aa) 1) and 20.4 aa) 2).

Item *d)*

Addition:

During the dielectric strength test, the test voltage in the high-voltage circuit should be kept as close as possible to 100 %, and is not to be outside the range of 100 % and 105 % of the value required.

Item *f)*

Addition:

During the dielectric strength test of HIGH-VOLTAGE GENERATORS slight corona discharges in the high-voltage circuit are to be disregarded if they cease when the test voltage is lowered to 110 % of the voltage to which the test condition is referred.

Item *l)*

Addition:

The test voltage for the dielectric strength testing of stator and stator circuit used for the operation of the rotating ANODE of the X-RAY TUBE is to be referred to the voltage existing after reduction of the stator supply voltage to its steady state operating value.

Additional item aa):

1) *HIGH-VOLTAGE GENERATORS or subassemblies thereof, that are integrated with an X-RAY TUBE ASSEMBLY are to be tested with an appropriately loaded X-RAY TUBE.*

2) *If such HIGH-VOLTAGE GENERATORS do not have separate adjustment of the X-RAY TUBE CURRENT, the duration of the dielectric strength test is to be reduced to such an extent that the allowable X-RAY TUBE LOAD at the increased X-RAY TUBE VOLTAGE will not be exceeded.*

3) *If the dielectric strength test is performed with an X-RAY TUBE connected and the high-voltage circuit is not accessible for the measurement of the test voltage applied, appropriate measures are to be taken to ensure that the values lie within the limits required in 20.4 d).*

SECTION 4: PROTECTION AGAINST MECHANICAL HAZARDS

The clauses and subclauses of this section of the General Standard apply except as follows:

Addition:

NOTE – Some parts attached to an X-RAY GENERATOR are considered to be ASSOCIATED EQUIPMENT and are covered by IEC 60601-2-32.

SECTION 5: PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

The clauses and subclauses of this section of the General Standard apply except as follows:

29 X-RADIATION

This clause of the General Standard applies except as follows:

29.1 *Replacement:*

29.1 X-RADIATION generated by diagnostic X-RAY GENERATORS containing HIGH-VOLTAGE GENERATORS

Addition:

29.1.101 General requirements

HIGH-VOLTAGE GENERATORS of diagnostic X-RAY GENERATORS shall comply with the applicable requirements of IEC 60601-1-3; see 1.3.101.

29.1.102 Indication of operational states

a) READY STATE in INTERMITTENT MODE

Visible indication shall be provided on the CONTROL PANEL indicating the state when one further actuation of a control from that CONTROL PANEL will initiate the LOADING of the X-RAY TUBE in INTERMITTENT MODE.

If this state is indicated in INTERMITTENT MODE by means of a single function indicator light, the colour green shall be used; see 6.7 a).

In INTERMITTENT MODE, means shall be provided for a connection to enable this state to be indicated remotely from the CONTROL PANEL. This requirement does not apply for X-RAY GENERATORS of MOBILE EQUIPMENT.

NOTE – The actuation of a single control with two consecutive positions – as used for starting a rotating anode and setting other preparatory conditions – is regarded as a single actuation.

b) LOADING STATE

The LOADING STATE shall be indicated by a yellow indicator light on the CONTROL PANEL of the HIGH-VOLTAGE GENERATOR; see 6.7 a). Additionally,

– in INTERMITTENT MODE, provision shall be made for the connection of a signalling device, audible at the location from which the EQUIPMENT is operated, to indicate the instant of termination of LOADING,

– in CONTINUOUS MODE, means shall be provided for connections to be made so that the LOADING STATE in CONTINUOUS MODE can be indicated remotely from the CONTROL PANEL. This requirement does not apply for X-RAY GENERATORS of MOBILE EQUIPMENT.

c) Indication of the X-RAY SOURCE ASSEMBLY selected

Where a HIGH-VOLTAGE GENERATOR has provisions to select more than one X-RAY TUBE, an indication of the X-RAY TUBE selected shall be provided on the CONTROL PANEL prior to the LOADING of the X-RAY TUBE.

Where a HIGH-VOLTAGE GENERATOR has provisions to initiate the LOADING of more than one X-RAY TUBE from a single location, means shall be provided for the connection of an additional indication to be given at or near each X-RAY TUBE selectable.

d) Indication of automatic modes

For HIGH-VOLTAGE GENERATORS operating with AUTOMATIC CONTROL SYSTEMS, the preselected mode of automatic operation shall be indicated on the CONTROL PANEL.

e) Ranges in AUTOMATIC EXPOSURE CONTROL

For HIGH-VOLTAGE GENERATORS operating in INTERMITTENT MODE in which AUTOMATIC EXPOSURE CONTROL is achieved by varying one or more LOADING FACTORS, information about the range and interrelation of these LOADING FACTORS shall be given in the INSTRUCTIONS FOR USE.

In addition, this information shall be provided in a form suitable to be displayed at a prominent location on or near the CONTROL PANEL of the HIGH-VOLTAGE GENERATOR.

Compliance is checked by inspection and by the appropriate functional tests.

29.1.103 Limitation of RADIATION output

a) Means shall be provided to limit the electric energy to be delivered by the use of fixed or preselected combinations of suitable LOADING FACTORS and modes of operation.

However, for modes of operation used in such techniques as RADIOSCOPY or CINERADIOGRAPHY, the duration of the LOADINGS may be under the continuous control of the OPERATOR.

b) Each LOADING shall be initiated and maintained by means of a control requiring continuous actuation by the OPERATOR.

c) It shall not be possible to initiate any subsequent IRRADIATION or, in SERIAL RADIOGRAPHY, any subsequent series without releasing the control by which the previous IRRADIATION was initiated.

d) Means shall be provided for the OPERATOR to terminate each LOADING at any time before its intended completion, except during SERIAL RADIOGRAPHY or for single LOADINGS with a LOADING TIME of 0,5 s or less.

During SERIAL RADIOGRAPHY, the OPERATOR shall be able to terminate the LOADINGS at any time, but means may be provided to permit completion of any single LOADING of the series in progress.

e) Any control by which the LOADING of an X-RAY TUBE can be initiated shall be safeguarded against unintended actuation.

NOTE – Safeguarding against unintended actuation is only possible insofar as the wearing of PROTECTIVE GLOVES or the use of footswitches remain practicable.

Compliance is checked by inspection and by the appropriate functional tests.

29.1.104 Safety measures against excessive RADIATION output

a) In the case of a failure of its normal termination, the IRRADIATION shall be terminated by a safety measure.

b) For operation in CONTINUOUS MODE, when the duration of IRRADIATION is determined by the OPERATOR while it is in progress, a TIMING DEVICE shall be provided to give an audible warning signal to the OPERATOR of the completion of accumulated periods of LOADING. The TIMING DEVICE shall have the following characteristics:

1) it shall be possible to set the timing period of the device so as to permit subsequent LOADINGS to accumulate a duration up to five minutes without any warning being given. Provision may also be made for periods shorter than five minutes to be set. Any LOADING made without the device having been set and any LOADING made subsequently to the expiry of its most recently set period shall cause an audible warning signal to be given continuously while such LOADING is taking place;

2) it shall be possible to reset the device at any time, without prevention or interruption of LOADING, in order to stop the warning and to permit further periods of LOADING, each not exceeding five minutes, to be accumulated, during which no warning is given;

3) any control for setting or resetting the time period shall be separate from any IRRADIATION SWITCH.

c) In addition to the TIMING DEVICE required in item b) above, means shall be provided to ensure automatic termination in the event of LOADING in CONTINUOUS MODE having continued without interruption for a period exceeding 10 min. In the event of termination being effected by these means in NORMAL CONDITION, it shall be possible to resume LOADING by releasing and re-actuating the IRRADIATION SWITCH.

d) In INTERMITTENT MODE, if the normal termination is not effected upon the basis of a RADIATION measurement, continuous actuation by the OPERATOR in accordance with 29.1.103 b) shall suffice as the safety measure required in item a) above.

e) In INTERMITTENT MODE if the normal termination depends upon a RADIATION measurement the safety measure shall comprise means for termination of IRRADIATION in the event of a failure of the normal termination.

Either the product of X-RAY TUBE VOLTAGE, X-RAY TUBE CURRENT and IRRADIATION TIME shall be limited to not more than 60 kJ per IRRADIATION or the CURRENT TIME PRODUCT shall be limited to no more than 600 mAs per IRRADIATION.

The system for normal termination of IRRADIATION and the system used for the safety measure shall be separated so that a failure in one system does not affect termination by the other system.

A visible indication at the CONTROL PANEL shall be provided whenever a LOADING has been terminated by the safety means required. Another LOADING in the same mode of operation shall not be possible until a control device provided for resetting has been operated at the CONTROL PANEL.

f) For HIGH-VOLTAGE GENERATORS provided with AUTOMATIC INTENSITY CONTROL or AUTOMATIC EXPOSURE CONTROL, a method by which the OPERATOR can verify the functioning of these controls shall be provided and the INSTRUCTIONS FOR USE shall contain the description of that method.

Compliance is checked by inspection and by the appropriate functional tests.

29.1.105 Connection of external INTERLOCKS

HIGH-VOLTAGE GENERATORS, except those of dental X-RAY GENERATORS and TRANSPORTABLE X-RAY GENERATORS, shall be provided with connections for external INTERLOCKS or other electrical devices that can be positioned remotely from the HIGH-VOLTAGE GENERATOR and can cause the X-RAY GENERATOR to stop emitting X-RADIATION and can prevent the X-RAY GENERATOR from starting to emit X-RADIATION.

NOTE – An example of the use of this facility would be to ensure the presence of PROTECTIVE SHIELDING during RADIOSCOPY.

Compliance is checked by inspection and by the appropriate functional tests.

29.1.106 Adequate range of LOADING FACTORS

a) General requirement

For all their specified applications, HIGH-VOLTAGE GENERATORS shall make available adequate ranges of combinations of LOADING FACTORS, so that the delivery of unnecessarily high ABSORBED DOSES to PATIENTS can be avoided.

b) Systems for automatic control of LOADING FACTORS shall provide an adequate range of combinations of preselectable LOADING FACTORS, so that the automatic control is applied in ranges enabling the general requirement in item a) to be met.

c) In HIGH-VOLTAGE GENERATORS specified for dental applications, the increments of scale values of X-RAY TUBE CURRENT or IRRADIATION TIME or CURRENT TIME PRODUCT shall be not greater than 25 %.

d) In HIGH-VOLTAGE GENERATORS specified for dental applications and operating at one X-RAY TUBE VOLTAGE only, the available CURRENT TIME PRODUCT shall cover a range in which the ratio of the highest to the lowest CURRENT TIME PRODUCT is at least 16. Corresponding ranges of CURRENT TIME PRODUCT values shall be covered if more than one X-RAY TUBE VOLTAGE can be used.

NOTE – It is recommended to use scale increments according to the R'10 series; see annex BB.

e) For IRRADIATION TIMES shorter than 0,063 s in ONE-PEAK HIGH-VOLTAGE GENERATORS and TWO-PEAK HIGH-VOLTAGE GENERATORS specified for dental applications where, because of dependence on the frequency of the SUPPLY MAINS, it is not possible to provide all values belonging to the geometrical series within the range, missing values and consequently different geometrical intervals between the values provided shall be recognisable on the scale, and shall be explained in the ACCOMPANYING DOCUMENTS.

f) In systems for automatic control of LOADING FACTORS in CONTINUOUS MODE the general requirement of item a) shall be considered to be met if

- at least two appropriately differentiated levels of the controlled quantity can be selected, or
- at least two appropriately differentiated levels of one characteristic LOADING FACTOR, or appropriately differentiated functions of interdepending LOADING FACTORS can be selected, or
- additionally, manual control without the use of the AUTOMATIC CONTROL SYSTEM is possible.

g) HIGH-VOLTAGE GENERATORS designed for RADIOSCOPY shall be provided with means for the available combinations of LOADING FACTORS in CONTINUOUS MODE to be restricted to correspond, in particular installations, to any limit applying to the maximum AIR KERMA RATE available from the X-RAY EQUIPMENT, in order to comply with local regulations.

When a high level control is provided, a continuous audible signal shall indicate that the high level control is actuated.

Compliance is checked by inspection and by the appropriate functional tests.

36 Electromagnetic compatibility

This clause of the General Standard applies except as follows:

Replacement:

IEC 60601-1-2 shall be applicable.

SECTION 6: PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

The clauses and subclauses of this section of the General Standard apply.

SECTION 7: PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

The clauses and subclauses of this section of the General Standard apply except as follows:

42 Excessive temperatures

This clause of the General Standard applies except as follows:

42.1 *Addition:*

Restrictions on allowable maximum temperature for parts in contact with oil shall not apply to parts wholly immersed in oil.

SECTION 8: ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

The clauses and subclauses of this section of the General Standard apply except as follows:

Addition:

NOTE – Many variable factors affect the relationship between the output parameters of a HIGH-VOLTAGE GENERATOR and the attainment of particular radiographic results in the X-RAY EQUIPMENT. Even when there is compliance with this standard, it is not to be expected in daily radiographic practice that LOADING FACTORS determined for any purpose on one installation can be transferred to other installations for the same purpose, without correction.

50 Accuracy of operating data

This clause of the General Standard applies except as follows:

Replacement:

50.1 General

For HIGH-VOLTAGE GENERATORS or subassemblies thereof it shall be possible to demonstrate compliance with the requirements of 50.102 and 50.103 by application of the relevant tests under the conditions of 50.104 and 50.105, in all combinations of subassemblies of an X-RAY GENERATOR that are specified in the ACCOMPANYING DOCUMENTS as being compatible for compliance with this standard.

Compliance of HIGH-VOLTAGE GENERATORS or subassemblies thereof with the requirements of 50.102 and 50.103 is to be tested in one or more suitable combinations with X-RAY TUBES and appropriate subassemblies of an X-RAY GENERATOR, specified in the ACCOMPANYING DOCUMENTS as suitable for this purpose.

50.101 Indication of electric and RADIATION output

50.101.1 General

a) Adequate information shall be available to the OPERATOR before, during and after the LOADING of an X-RAY TUBE, about fixed, permanently or semi-permanently preselected or otherwise predetermined, LOADING FACTORS or modes of operation so as to enable the OPERATOR to preselect appropriate conditions for the IRRADIATION and subsequently to obtain data necessary for the estimation of the ABSORBED DOSE received by the PATIENT; see 50.101.2 and 50.101.3.

Discrete values of indicated LOADING FACTORS having an essentially proportional relation to the amount of X-RADIATION produced, particularly values for X-RAY TUBE CURRENT, LOADING TIME and CURRENT TIME PRODUCT, shall be chosen from the series R'10 or R'20 according to ISO 497.

If compliance with this standard of LOADING FACTORS indicated in a series R'10 is to be determined by using the theoretical (calculated) values according to annex BB, this shall be indicated in the ACCOMPANYING DOCUMENTS.

b) In HIGH-VOLTAGE GENERATORS for dental RADIOGRAPHY with OBJECT PROGRAMMED CONTROL, the following requirements apply to adjustments provided to compensate for the variable sensitivity of recording media by controlling the X-RAY TUBE CURRENT or the IRRADIATION TIME:

1) the available range of adjustment of the controlled parameter shall not be less than 4 to 1;

2) the values of the controlled parameter resulting from adjacent settings of the adjustment shall be in the series R'10 with an interval of 1,25 or 1,6.

c) The units of indication shall be as follows:

- for X-RAY TUBE VOLTAGE, kilovolts;
- for X-RAY TUBE CURRENT, milliamperes;
- for LOADING TIME, seconds;
- for IRRADIATION TIME, seconds;
- for CURRENT TIME PRODUCT, milliampereseconds;
- in CONTINUOUS MODE for RADIOSCOPY, the IRRADIATION TIME may be indicated decimally in minutes.

d) *Compliance with the requirements of 50.101.1 a) to 50.101.1 c) is checked by inspection.*

50.101.2 Shortened indication

a) For HIGH-VOLTAGE GENERATORS operating with one or more fixed combinations of LOADING FACTORS the indication on the CONTROL PANEL may be confined to the value of only one of the significant LOADING FACTORS for each combination, for example the value of X-RAY TUBE VOLTAGE.

In this case, the indication of the corresponding values of the other LOADING FACTORS in each combination shall be given in the INSTRUCTIONS FOR USE.

In addition, these values shall be listed in a form suitable to be displayed at a prominent location on or near the CONTROL PANEL.

b) For HIGH-VOLTAGE GENERATORS operating with fixed combinations of semi-permanently preselectable LOADING FACTORS, the indication on the CONTROL PANEL may be confined to a clear reference to the identity of each combination.

In this case, provisions shall be made to enable

- the values of each combination of semi-permanently preselected LOADING FACTORS set at the time of installation to be recorded in the INSTRUCTIONS FOR USE, and in addition to enable
- the values to be listed in a suitable form to be displayed at a prominent location on or near the CONTROL PANEL.

50.101.3 Indication of varying LOADING FACTORS

For HIGH-VOLTAGE GENERATORS operating with AUTOMATIC INTENSITY CONTROL in RADIOSCOPY, continuous indication of the LOADING FACTORS that vary shall be given at the CONTROL PANEL.

50.102 Reproducibility, linearity and constancy

NOTE – 50.101 and 50.102 contain requirements on operating data for diagnostic HIGH-VOLTAGE GENERATORS, as part of X-RAY GENERATORS, that are considered essential for protection against incorrect output. HIGH-VOLTAGE GENERATORS of higher performance are often necessary to ensure the consistent attainment of desired levels of diagnostic capability.

50.102.1 Reproducibility of the RADIATION output in INTERMITTENT MODE without AUTOMATIC EXPOSURE CONTROL activated

The coefficient of variation of MEASURED VALUES of AIR KERMA shall be not greater than 0,05 for any combination of LOADING FACTORS.

Compliance is determined by tests according to 50.104, 50.105 and table 105, in suitable test combinations; see 50.1.

50.102.2 Linearity and constancy in INTERMITTENT MODE

a) Linearity of AIR KERMA over limited intervals of LOADING FACTORS

For operation in INTERMITTENT MODE the quotients of the average of the MEASURED VALUES of AIR KERMA divided by the preselected values or the indicated values of CURRENT TIME PRODUCT, or the product of the values of X-RAY TUBE CURRENT and IRRADIATION TIME, obtained at any two settings of the above LOADING FACTORS when preselection is continuous and the preselected values differ by a factor as close as possible to but not exceeding 2, shall not differ by more than 0,2 times the mean value of these quotients:

$$\left| \frac{\overline{K}_1}{Q_1} - \frac{\overline{K}_2}{Q_2} \right| \leq 0{,}2 \frac{\frac{\overline{K}_1}{Q_1} + \frac{\overline{K}_2}{Q_2}}{2}$$

$$\left| \frac{\overline{K}_1}{I_1 t_1} - \frac{\overline{K}_2}{I_2 t_2} \right| \leq 0{,}2 \frac{\frac{\overline{K}_1}{I_1 t_1} + \frac{\overline{K}_2}{I_2 t_2}}{2}$$

where

$\overline{K}_1$, $\overline{K}_2$ are the averages of the MEASURED VALUES of AIR KERMA;

Q_1 and Q_2 are the indicated CURRENT TIME PRODUCTS;

I_1 and I_2 are the indicated X-RAY TUBE CURRENTS;

t_1 and t_2 are the indicated IRRADIATION TIMES.

Compliance is determined by tests according to 50.104, 50.105 and table 105, in suitable test combinations; see 50.1.

b) Constancy of AUTOMATIC EXPOSURE CONTROLS

In the operation of an AUTOMATIC EXPOSURE CONTROL in INTERMITTENT MODE to control IRRADIATION for DIRECT RADIOGRAPHY, the variation of optical density in the resultant RADIOGRAMS shall not exceed a value of

1) 0,15 arising from changes of the X-RAY TUBE VOLTAGE, the thickness of the irradiated object being constant,

2) 0,20 arising from changes in the thickness of the irradiated object, the X-RAY TUBE VOLTAGE being constant,

3) 0,20 arising from changes in both the X-RAY TUBE VOLTAGE and the thickness of the irradiated object,

4) 0,10 for unchanged X-RAY TUBE VOLTAGE and constant thickness of the irradiated object.

The above requirements do not apply to AUTOMATIC EXPOSURE CONTROLS designed for use in DENTAL PANORAMIC TOMOGRAPHY.

Compliance is determined by the following test.

aa) *Method*

Measure the optical density of RADIOGRAMS of PHANTOMS made of water or other TISSUE EQUIVALENT MATERIAL, produced with the AUTOMATIC EXPOSURE CONTROL in operation. Determine the variations of density for different PHANTOM thicknesses and for different X-RAY TUBE VOLTAGES.

bb) *Test arrangement*

Use a test arrangement with the following characteristics; see also figure 102:

1) *a FOCAL SPOT TO IMAGE RECEPTOR DISTANCE of 100 cm, remaining unchanged for all tests in a series;*

2) *an 18 × 24 RADIOGRAPHIC CASSETTE as X-RAY IMAGE RECEPTOR, the same cassette being used for all tests in a series;*

3) *an X-RAY SOURCE ASSEMBLY of a type specified for use with the HIGH-VOLTAGE GENERATOR under test. The X-RAY FIELD is aligned and adjusted to 18 cm × 24 cm at the ENTRANCE SURFACE of the cassette and remains unchanged for all tests in a series;*

4) *provision for mounting the measuring chamber of the AUTOMATIC EXPOSURE CONTROL in a manner and position corresponding to NORMAL USE;*

5) *provision of PHANTOMS of three different thicknesses, 10 cm, 15 cm and 20 cm, each of a size to cover the cassette fully, the PHANTOM in use for a particular test being mounted as close as possible to the ENTRANCE SURFACE of the cassette;*

6) *provision of a FOCUSED GRID having the appropriate APPLICATION LIMITS;*

7) *provision for accurate and reproducible film processing and for measuring the optical density of the processed films.*

cc) *RADIOGRAPHIC FILM and INTENSIFYING SCREEN*

Use a combination of RADIOGRAPHIC FILM with a gradient close to 2 and an INTENSIFYING SCREEN of a type specified to be suitable for NORMAL USE of the AUTOMATIC EXPOSURE CONTROL.

For any one series of tests, select pieces of film from the same batch, for which consistency of characteristics has been verified.

dd) *Setting the AUTOMATIC EXPOSURE CONTROL*

1) *Select the central field of the measuring chamber of the AUTOMATIC EXPOSURE CONTROL.*

2) *Make any adjustments required in accordance with the INSTRUCTIONS FOR USE to apply the density correction for the type of film-screen combination in use and to produce a measured optical density in the processed film of 1,1 to 1,3, when operating at an X-RAY TUBE VOLTAGE of 80 kV, using the 15 cm PHANTOM.*

ee) *Selecting the X-RAY TUBE CURRENT*

Except when testing an AUTOMATIC EXPOSURE CONTROL that operates with a fixed IRRADIATION TIME, select a value of X-RAY TUBE CURRENT that will result in IRRADIATION TIMES during the tests exceeding three times the shortest specified IRRADIATION TIME but not exceeding 1 s. Record any selected value.

If no suitable value of X-RAY TUBE CURRENT can be selected, use a different FOCAL SPOT TO IMAGE RECEPTOR DISTANCE to enable the stated range of IRRADIATION TIMES to be achieved with the nearest available setting of X-RAY TUBE CURRENT.

ff) *Test LOADINGS*

Make eight test LOADINGS, using the combinations of X-RAY TUBE VOLTAGE and PHANTOM thickness indicated in table 103 and four additional LOADINGS at 80 kV with 15 cm PHANTOM thickness. Process the films; measure and record the optical density of each image.

Table 103 – LOADINGS for testing AUTOMATIC EXPOSURE CONTROLS

X-RAY TUBE VOLTAGE (see note 1) *kV*	*PHANTOM thicknesses* *cm*
60 (see note 2)	*10 and 15*
80	*15 and 20*
100	*15 and 20*
120 (see note 2)	*10 and 15*

NOTE 1 – If any of these values are not selectable, use the nearest selectable value.

NOTE 2 – If this value is outside the specified range, use the nearest value within the specified range and select other values as evenly spaced as possible in the reduced range.

gg) *Compliance criteria*

Compliance is achieved if

1) *for the four LOADINGS made with the 15 cm PHANTOM, no MEASURED VALUE of optical density differs by more than 0,15 from the mean of the four values and no value differs by more than 0,15 from the value for an adjacent step of X-RAY TUBE VOLTAGE,*

2) *for each of the four pairs of LOADINGS made at the same X-RAY TUBE VOLTAGE (with PHANTOMS of different thickness), no MEASURED VALUE of optical density differs by more than 0,2 from the other value in the pair,*

3) *for the whole series of eight LOADINGS, no MEASURED VALUE of optical density differs by more than 0,2 from the mean of the eight values,*

4) *for five loadings at constant test parameters, 80 kV with 15 cm PHANTOM thickness, no MEASURED VALUE of optical density differs by more than 0,1 from the mean value of the five values.*

50.103 Accuracy of LOADING FACTORS

NOTE – 50.101 and 50.102 contain requirements on operating data for diagnostic HIGH-VOLTAGE GENERATORS, as part of X-RAY GENERATORS, that are considered essential for protection against incorrect output. HIGH-VOLTAGE GENERATORS of higher performance are often necessary to ensure the consistent attainment of desired levels of diagnostic capability.

In X-RAY GENERATORS with AUTOMATIC CONTROL SYSTEMS where the X-RAY TUBE VOLTAGE or the X-RAY TUBE CURRENT, or both, is intended to vary during the IRRADIATION, the accuracy of the intentionally varied LOADING FACTOR required in 50.103.1 and 50.103.2, shall be disregarded.

In HIGH-VOLTAGE GENERATORS the requirements of this subclause apply to the accuracy of all values of LOADING FACTORS, whether indicated, fixed or preselected when compared with MEASURED VALUES of the same LOADING FACTOR.

Compliance is determined by tests according to 50.104.

50.103.1 Accuracy of X-RAY TUBE VOLTAGE

For operation of a HIGH-VOLTAGE GENERATOR in any specified combination with subassemblies and components of an X-RAY GENERATOR, the error of the value of the X-RAY TUBE VOLTAGE, in any combination of LOADING FACTORS, shall be not greater than 10 %.

The increment or decrement of the X-RAY TUBE VOLTAGE between any two indicated settings shall be within 50 % and 150 % of the indicated change.

50.103.2 Accuracy of X-RAY TUBE CURRENT

For operation of HIGH-VOLTAGE GENERATORS in any specified combination with subassemblies and components of an X-RAY GENERATOR, the error of the value of the X-RAY TUBE CURRENT, in any combination of LOADING FACTORS, shall be not greater than 20 %.

50.103.3 Accuracy of LOADING TIME

For operation of HIGH-VOLTAGE GENERATORS in any specified combination with subassemblies and components of an X-RAY GENERATOR, the error of the value of the X-RAY TUBE LOADING TIME, in any combination of LOADING FACTORS, shall be not greater than ± (10 % + 1 ms).

50.103.4 Accuracy of CURRENT TIME PRODUCT

For operation of HIGH-VOLTAGE GENERATORS in any specified combination with subassemblies and components of an X-RAY GENERATOR, the error of the value of the X-RAY TUBE CURRENT TIME PRODUCT, in any combination, shall be not greater than ± (10 % + 0,2 mAs).

This requirement also applies in cases when the CURRENT TIME PRODUCT is derived by calculation.

50.104 Test conditions

Tests for compliance of LOADING FACTORS with the requirements of 50.102 and 50.103 shall be conducted under the following conditions.

A survey of the following minimum required combinations of LOADING FACTORS is given in annex CC.

50.104.1 X-RAY TUBE VOLTAGE

a) INTERMITTENT MODE

One measurement shall be made at the lowest INDICATED VALUE of X-RAY TUBE VOLTAGE, the highest available X-RAY TUBE CURRENT for that X-RAY TUBE VOLTAGE and the shortest INDICATED VALUE of IRRADIATION TIME.

One measurement shall be made at the lowest INDICATED VALUE of X-RAY TUBE VOLTAGE, the highest available X-RAY TUBE CURRENT for that X-RAY TUBE VOLTAGE and an IRRADIATION TIME of approximately 0,1 s.

One measurement shall be made at the highest INDICATED VALUE of X-RAY TUBE VOLTAGE and the highest available X-RAY TUBE CURRENT for that X-RAY TUBE VOLTAGE and an IRRADIATION TIME of approximately 0,1 s.

b) CONTINUOUS MODE

One measurement shall be made at 90 % of the maximum available X-RAY TUBE VOLTAGE and any X-RAY TUBE CURRENT.

One measurement shall be made at 60 % of the maximum available X-RAY TUBE VOLTAGE and any X-RAY TUBE CURRENT.

50.104.2 X-RAY TUBE CURRENT

a) INTERMITTENT MODE

One measurement shall be made at the lowest INDICATED VALUE of X-RAY TUBE CURRENT, the highest INDICATED VALUE of X-RAY TUBE VOLTAGE and the shortest INDICATED VALUE of IRRADIATION TIME.

One measurement shall be made at the lowest INDICATED VALUE of X-RAY TUBE CURRENT, the highest INDICATED VALUE of X-RAY TUBE VOLTAGE and an IRRADIATION TIME of approximately 0,1 s.

One measurement shall be made at the highest INDICATED VALUE of X-RAY TUBE CURRENT, the highest available X-RAY TUBE VOLTAGE for the tested X-RAY TUBE CURRENT and an IRRADIATION TIME of approximately 0,1 s.

b) CONTINUOUS MODE

One measurement shall be made at 20 % of the maximum available X-RAY TUBE CURRENT and the lowest available X-RAY TUBE VOLTAGE.

One measurement shall be made at 20 % of the maximum available X-RAY TUBE CURRENT and the highest available X-RAY TUBE VOLTAGE.

50.104.3 *IRRADIATION TIME*

a) Determination of the IRRADIATION TIME

One measurement shall be made at the lowest INDICATED VALUE of IRRADIATION TIME, the highest INDICATED VALUE of X-RAY TUBE VOLTAGE and any INDICATED VALUE of X-RAY TUBE CURRENT.

One measurement shall be made at the lowest INDICATED VALUE of IRRADIATION TIME and the highest available electric power, P.

b) Determination of the NOMINAL SHORTEST IRRADIATION TIME

Make an IRRADIATION using the AUTOMATIC EXPOSURE CONTROL with > 70 % of the available generator power at approximately 80 kV. To determine the average AIR KERMA, adjust the ATTENUATION in the X-RAY BEAM (preferably by using a water PHANTOM) to achieve an IRRADIATION TIME close to 0,1 s.

Make several IRRADIATIONS with reduced PHANTOM thicknesses using the same X-RAY TUBE VOLTAGE and generator power as mentioned above. The PHANTOM thickness shall be varied in such a way that the IRRADIATION TIME does not vary more than a factor of two between two IRRADIATIONS.

The NOMINAL SHORTEST IRRADIATION TIME is determined as the IRRADIATION TIME:

– for a LOADING during which the average AIR KERMA attained does not differ by more than 20 % from the average AIR KERMA attained for an IRRADIATION TIME at least 50 times greater, when measured in accordance with 50.105, and

– which is no shorter than the shortest IRRADIATION TIME for which the requirements for constancy are met in accordance with 50.102.2 b) 2).

50.104.4 CURRENT TIME PRODUCT

One measurement shall be made at the lowest INDICATED VALUE of CURRENT TIME PRODUCT and the highest available X-RAY TUBE VOLTAGE.

One measurement shall be made at the highest INDICATED VALUE of CURRENT TIME PRODUCT and the lowest available X-RAY TUBE VOLTAGE.

50.105 Conditions for measuring AIR KERMA

50.105.1 Measuring arrangements

Arrange the HIGH-VOLTAGE GENERATOR or subassembly under test in a suitable combination with an X-RAY SOURCE ASSEMBLY (and, if applicable, with other subassemblies needed to constitute an X-RAY GENERATOR) specified in the ACCOMPANYING DOCUMENTS of the unit under test as suitable for this purpose.

Align the X-RAY SOURCE ASSEMBLY, the DIAPHRAGM and the RADIATION DETECTOR under NARROW BEAM CONDITION according to figure 101, as applicable.

Arrange the attenuating material needed according to figure 101 or select the attenuating material specified in 50.105.2 b). Verify the RADIATION QUALITY according to 50.105.2 a).

50.105.2 ATTENUATION and RADIATION QUALITY for measurement of AIR KERMA

a) RADIATION QUALITY

Ensure that the RADIATION QUALITY of the X-RAY BEAM emerging from the X-RAY SOURCE ASSEMBLY complies with applicable specified conditions for NORMAL USE. If no such conditions are specified, ensure that the TOTAL FILTRATION in the X-RAY SOURCE ASSEMBLY is such as to comply with the HALF-VALUE LAYER requirements in IEC 60601-1-3, table 204, as applicable.

Table 104 – ATTENUATION for the measurement of AIR KERMA

X-RAY TUBE VOLTAGE kV	Thickness of aluminium mm
40	4
50	10
60	16
70	21
80	26
90	30
100	34
120	40
150	45
NOTE – For intermediate values of X-RAY TUBE VOLTAGE, use the thickness given for the next higher stated value.	

b) ATTENUATION

To simulate the presence of a PATIENT during the measurement of AIR KERMA, add a layer of aluminium of sufficient size to intercept the whole of the X-RAY BEAM, the thickness being as follows:

- 6 mm for X-RAY GENERATORS specified for dental applications;
- in other cases, a thickness related to the selected X-RAY TUBE VOLTAGE in accordance with table 104.

50.105.3 Tests for verifying reproducibility

Make 10 measurements of AIR KERMA in one hour, at each of the test settings A, B, C and D according to table 105.

Calculate the coefficient of variation for each of the measurement series and the average AIR KERMA for test settings C and D, to verify compliance according to 50.102.1.

50.105.4 Tests for verifying linearity

Make 10 measurements of AIR KERMA in one hour, at each of the test settings E and F according to table 105.

Calculate the average value of AIR KERMA for the two measurements series. Use these average values and those for test settings C and D from 50.105.3 to verify compliance according to the formula in 50.102.2 a).

Table 105 – Tests for verifying reproducibility and linearity

Test setting	A	B	C	D	E	F
X-RAY TUBE VOLTAGE	Lowest	Highest	50 % of highest	80 % of highest	50 % of highest	80 % of highest
X-RAY TUBE CURRENT or CURRENT TIME PRODUCT*	Highest	Lowest	Giving 1 µGy – 5 µGy		Adjacent to setting for C and D	
IRRADIATION TIME*	Between 0,01 s and 0,32 s for all settings					

* As available with the settings defined in previous rows.

51 Protection against hazardous output

This clause of the General Standard applies except as follows:

Replacement:

Protection against incorrect output is considered to exist by compliance with 29.1.104, 50.102 and 50.103.

SECTION 9: ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

The clauses and subclauses of this section of the General Standard apply.

SECTION 10: CONSTRUCTIONAL REQUIREMENTS

The clauses and subclauses of this section of the General Standard apply except as follows:

56 Components and general assembly

This clause of the General Standard applies except as follows:

56.7 Batteries

Addition:

56.7.101 Charging mode INTERLOCK

Every MOBILE X-RAY EQUIPMENT having an incorporated battery charger shall be provided with means whereby powered movements and the generation of X-RADIATION by unauthorized persons can be prevented without preventing the charging of batteries.

NOTE – An example of suitable means to comply with this requirement is the provision of a key operated switch arranged so that powered movements and the generation of X-RADIATION are possible only when the key is present but battery charging is also possible in the absence of the key.

57 MAINS PARTS, components and layout

This clause of the General Standard applies except as follows:

57.10 CREEPAGE DISTANCES and AIR CLEARANCES

a) Values

Addition:

For X-RAY GENERATORS of PERMANENTLY INSTALLED X-RAY EQUIPMENT the values of table XVI of the General Standard for the insulation A-a1 and A-a2 of CLASS I EQUIPMENT apply up to a reference voltage of 660 V in a.c. r.m.s. or 800 V d.c.

For higher reference voltages, the CREEPAGE DISTANCES and AIR CLEARANCES

– shall be not less than those for 660 V a.c. r.m.s. and 800 V d.c. given in table XVI of the General Standard, and

– shall comply with the requirements according to 20.3 of the General Standard on dielectric strength for

Reference voltages	Test voltages
$660\ \text{V} < U \leq 1\,000\ \text{V}$	$2U + 1\,000\ \text{V}$
$1\,000\ \text{V} < U \leq 10\,000\ \text{V}$	$U + 2\,000\ \text{V}$

The dielectric strength test shall be performed under environmental conditions as described in 20.4 of the General Standard.

NOTE – For X-RAY EQUIPMENT installed with fixed and permanently installed PROTECTIVE EARTH CONDUCTOR it is assumed that there is no risk with regard to the reliability of the protective earth connection. For the same reason there is a statement in 19.3 e) of the General Standard that under these circumstances a higher EARTH LEAKAGE CURRENT is admissible. This aligns with the statements on CREEPAGE DISTANCES and AIR CLEARANCES in IEC 60664-1.

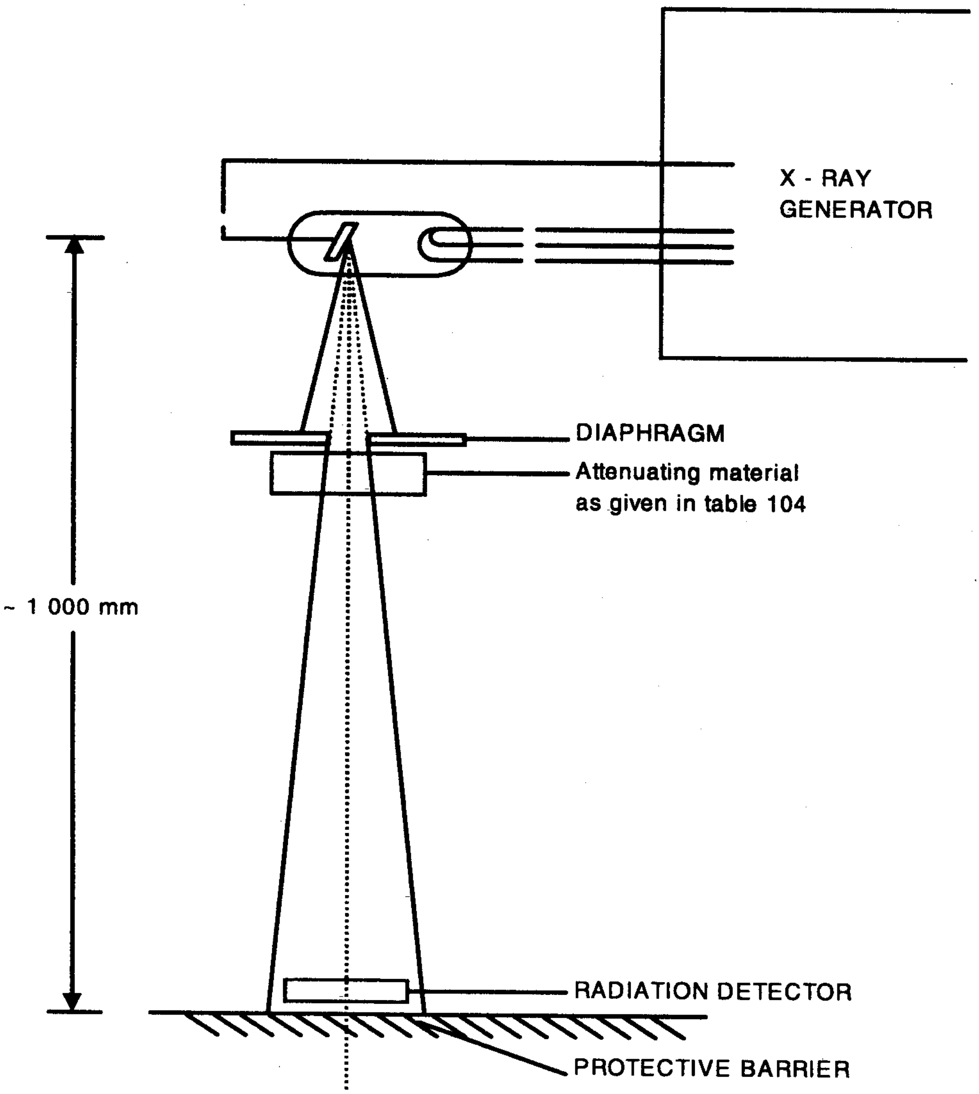

Figure 101 – Recommended arrangement for measuring AIR KERMA

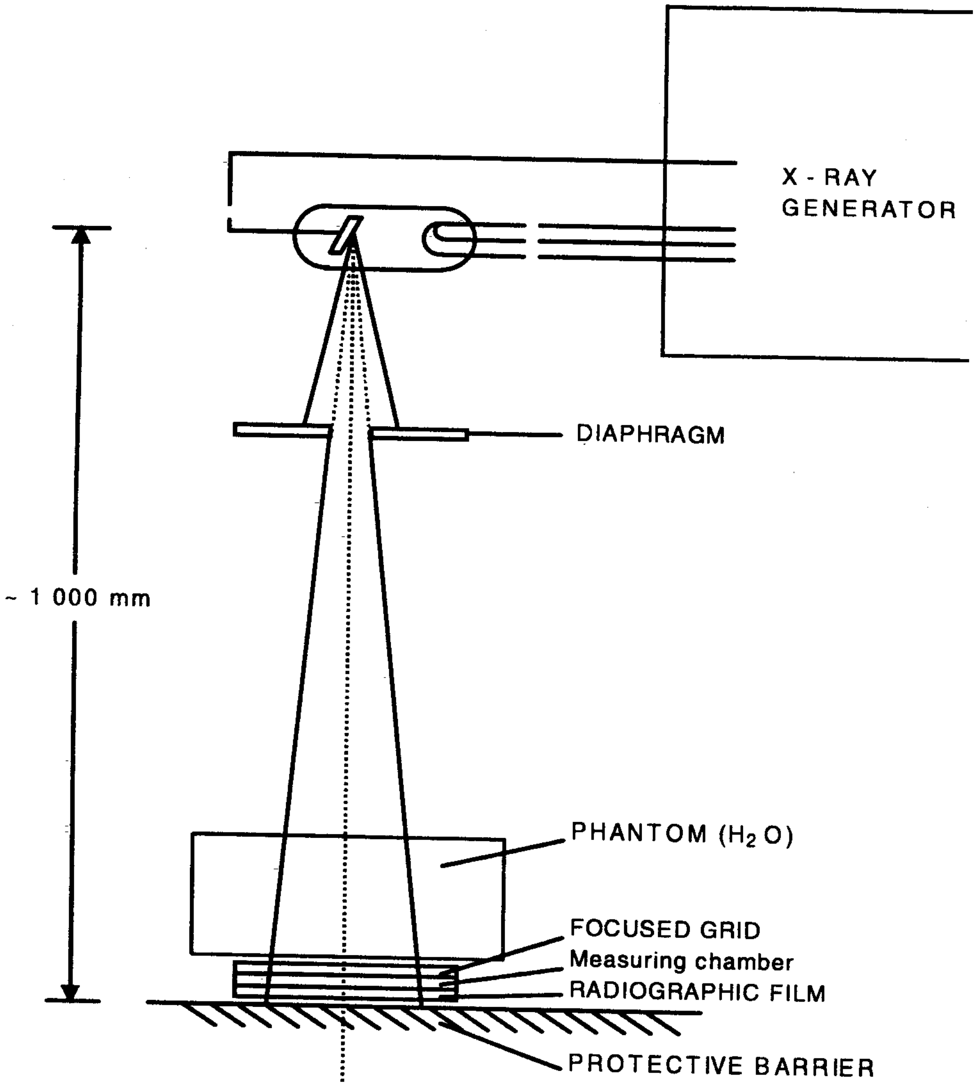

Figure 102 – Recommended arrangement for film density testing AUTOMATIC CONTROL SYSTEMS provided with a TRANSMISSION CHAMBER

Annex AA
(normative)

Terminology – Index of defined terms

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IEC 60788	rm-..-..
Name of unit in the International System SI	rm-..-..*
Derived term without definition	rm-..-..+
Term without definition	rm-..-..-
Name of earlier unit	rm-..-..Ǝ
Shortened term	rm-..-..s

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NOMINAL (value) NG-2.12.3
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PROTECTIVE EARTH CONDUCTOR NG-2.6.7
PROTECTIVE EARTH TERMINAL NG-2.6.8
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PROTECTIVE SHIELDING rm-64-01

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X-RAY TUBE ASSEMBLY ... rm-22-01
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X-RAY TUBE HEAD ... rm-20-07
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Annex BB
(normative)

Values of the series R'10 and R'20, ISO 497

The values, which shall be used according to 50.101.1 a) and 50.101.1 b), for marking and indication in fixed gradations of LOADING FACTORS having an essentially proportional relation to the amount of RADIATION received, shall be chosen as decimal multiples and submultiples from the following rounded values of the series R′10 and R′20.

Calculated values	R′10	R′20
1,0000	1,00	1,00
1,1220	–	1,10
1,2589	1,25	1,25
1,4125	–	1,40
1,5849	1,60	1,60
1,7783	–	1,80
1,9953	2,00	2,00
2,2387	–	2,20
2,5119	2,50	2,50
2,8184	–	2,80
3,1623	3,20	3,20
3,5481	–	3,60
3,9811	4,00	4,00
4,4668	–	4,50
5,0119	5,00	5,00
5,6234	–	5,60
6,3096	6,30	6,30
7,0795	–	7,10
7,9433	8,00	8,00
8,9125	–	9,00

Annex CC
(informative)

Choosing LOADING FACTORS for tests

In the testing of HIGH-VOLTAGE GENERATORS by applying LOADINGS to an X-RAY TUBE ASSEMBLY of a type with which the HIGH-VOLTAGE GENERATOR is specified to be used, there are severe practical limitations to the number of LOADINGS that can be applied. At no time during testing should the ratings of the X-RAY TUBE ASSEMBLY be exceeded. This applies not only to single LOADINGS but also to the accumulated effect of repeated LOADINGS on the ANODE HEAT CONTENT and on the X-RAY TUBE ASSEMBLY HEAT CONTENT. The need to allow time for cooling between LOADINGS is likely to be a significant factor in determining the total time required to determine compliance with this standard. It is, therefore, important to plan the tests in such a way that compliance can be verified with a reasonable minimum number of LOADINGS, otherwise the duration and cost of testing can become excessive. When no values for the LOADING FACTORS to be used are specifically stated in the descriptions of tests given in this standard, it is to be understood that the tester may choose any value of available LOADING FACTORS. It is recommended, however, that combinations of LOADING FACTORS used in the tests should include those representing the expected "worst case" conditions. If measurements at these combinations are favourable to compliance, additional confirmatory measurements may be made at other values of available LOADING FACTORS. As a general rule, it is recommended that no more than three points should need to be verified in any given range of required compliance, additionally to the initial "worst-case" points. As far as possible, LOADING FACTORS should be chosen, and measurements made, so as to take into account all the requirements for which information is required, rather than only one requirement at a time.

The "worst-case" conditions for compliance with a given requirement may depend on the technical features of the design. In the interests of reducing the cost of testing for compliance, it is recommended that MANUFACTURERS should make available all relevant information, so as to enable testers to verify compliance with a reasonable minimum number of test points. Tables CC.1 and CC.2 contain recommended combinations of LOADING FACTORS to be used in testing for compliance with 50.102 and 50.103 in the absence of information to the contrary.

The MAINS VOLTAGE used for the tests should be 90 % of the RATED voltage, with an APPARENT RESISTANCE OF SUPPLY MAINS at the maximum specified value, or the applicable value in table 101, whichever is the greater.

Table CC.1 – Recommended LOADING FACTORS for the testing of accuracy

LOADING FACTOR under test	X-RAY TUBE VOLTAGE	X-RAY TUBE CURRENT	IRRADIATION TIME
X-RAY TUBE VOLTAGE (INTERMITTENT MODE)	* lowest	highest	shortest
	* lowest	highest	0,1 s approx.
	* highest	highest	0,1 s approx.
X-RAY TUBE VOLTAGE (CONTINUOUS MODE)	* 90 % of highest	any	n/a
	* 60 % of highest	any	n/a
X-RAY TUBE CURRENT (INTERMITTENT MODE)	highest	* lowest	shortest
	highest	* lowest	0,1 s approx.
	highest	* highest	0,1 s approx.
X-RAY TUBE CURRENT (CONTINUOUS MODE)	lowest	* 20 % of highest	n/a
	highest	* 20 % of highest	n/a
IRRADIATION TIME	highest	any	* shortest
	highest electric power		* shortest
CURRENT TIME PRODUCT	highest	* lowest CURRENT TIME PRODUCT	
	lowest	* highest CURRENT TIME PRODUCT	

NOTE – * denotes the setting of an available INDICATED VALUE of the LOADING FACTOR under test. The values of other LOADING FACTORS in the same row are settings available in conjunction with this setting of the LOADING FACTOR under test.

Table CC.2 – Test settings for measurement of AIR KERMA

Test setting	X-RAY TUBE VOLTAGE	IRRADIATION TIME	Measured AIR KERMA	X-RAY TUBE CURRENT or CURRENT TIME PRODUCT
A	lowest	0,01 s – 0,32 s		highest applicable
B	highest	0,01 s – 0,32 s		lowest applicable
C	50 % of highest	0,01 s – 0,32 s	1 μGy – 5 μGy	set as required
D	80 % of highest	0,01 s – 0,32 s	1 μGy – 5 μGy	set as required
E	50 % of highest	0,01 s – 0,32 s		set adjacent to setting for C
F	80 % of highest	0,01 s – 0,32 s		set adjacent to setting for D

NOTE 1 – Settings A to D are for testing reproducibility, settings E and F are for testing linearity and constancy.

NOTE 2 – The test procedure requires each combination of LOADING FACTORS to be reset to the chosen values before each of ten LOADINGS.

These recommendations apply where the object of testing is only to verify compliance with this standard in a HIGH-VOLTAGE GENERATOR for which compliance is claimed by its MANUFACTURER. They do not apply to tests carried out for other purposes, for example to obtain information about the performance of a design, or to investigate in detail areas in which non-compliance has been discovered.

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